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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,856

11/21/2006

Jacques Defaye

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5988

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YOUNG & THOMPSON
745 SOUTH 23RD STREET
2ND FLOOR
ARLINGTON, VA 22202

EXAMINER

LAU, JONATHAN S

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

02/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,856	Applicant(s) DEFAYE ET AL.	
	Examiner Jonathan S. Lau	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-43 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 21-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Restriction Requirement

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 21-27 (in part), 28-30, 31 (in part), 32, 33 (in part), 34 (in part), 38 (in part), 40 (in part) and 42 (in part), drawn to a cyclodextrin dimer corresponding to the general formula (I) containing a biological recognition element, methods of making thereof, and pharmaceutical compositions thereof.

Group II, claim(s) 21-27 (in part), 31 (in part), 33 (in part), 34 (in part), 38 (in part), 40 (in part) and 42 (in part), drawn to drawn to a cyclodextrin dimer corresponding to the general formula (I) not containing a biological recognition element, methods of making thereof, and pharmaceutical compositions thereof.

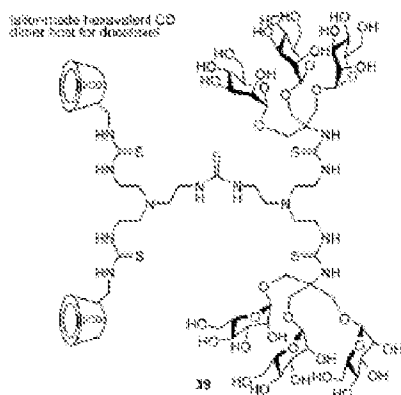
Group III, claim(s) 35-37(in part), 39 (in part), 41 (in part) and 43 (in part), drawn to pharmaceutical composition comprising a complex of a pharmacologically active agent and a cyclodextrin dimer corresponding to the general formula (I) containing a biological recognition element.

Group IV, claim(s) 35-37(in part), 39 (in part), 41 (in part) and 43 (in part), drawn to pharmaceutical composition comprising a complex of a pharmacologically active agent and a cyclodextrin dimer corresponding to the general formula (I) not containing a biological recognition element.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common feature of the inventions of Groups I-IV is the cyclodextrin dimer corresponding to the general

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formula (I). However, such a cyclodextrin dimer is a known compound. For example, see Benito et al. (Journal of the American Chemical Society, 2004, 126, p10355-10363, published on Web 04 Aug 2004, cited in PTO-892), page 10361, right column,



compound 39 in figure 5:

. Therefore said cyclodextrin

dimer is not the special technical feature of a single general inventive concept. The special technical feature of Group I is the specific chemical structure of a specific cyclodextrin dimer corresponding to the general formula (I) containing a specific biological recognition element. The special technical feature of Group II is the specific chemical structure of a specific cyclodextrin dimer corresponding to the general formula (I) not containing a biological recognition element. The special technical feature of Group III is the specific chemical structure of a complex of a specific pharmacologically active agent and a specific cyclodextrin dimer corresponding to the general formula (I) containing a biological recognition element. The special technical feature of Group III is the specific chemical structure of a complex of a specific pharmacologically active agent and a specific cyclodextrin dimer corresponding to the general formula (I) not containing a biological recognition element.

Election of Species Requirement

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In addition to restricting to the inventions of Groups I, II, III or IV, Applicant is further required to elect from the following election of species requirement.

If Applicant restricts to the invention of Group I or III, Applicant is required to elect from the **first** election of species requirement.

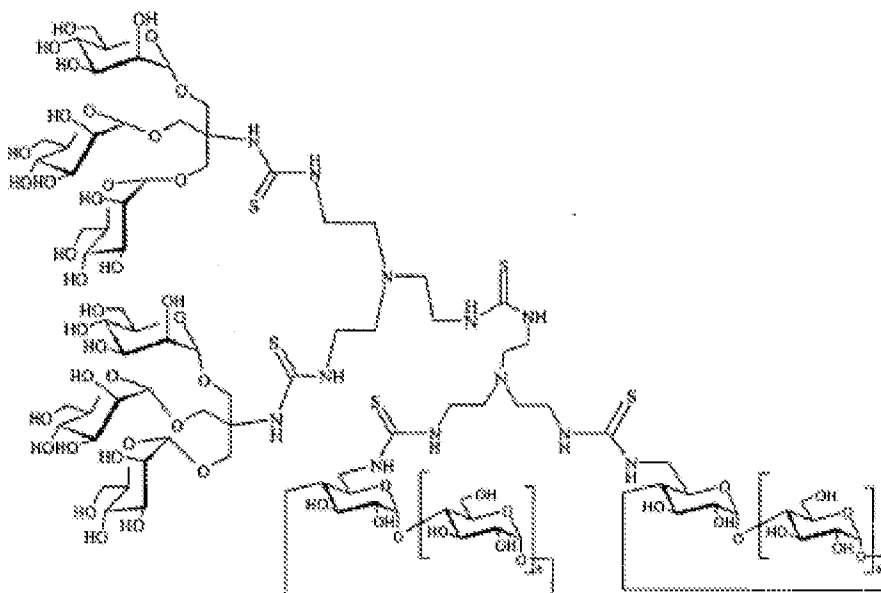
If Applicant restricts to the invention of Group II or IV, Applicant is required to elect from the **second** election of species requirement.

If Applicant restricts to the invention of Group I or III, Applicant is required to elect from the **first** election of species requirement.

First election of species requirement:

This application contains claims directed to more than one species of the generic invention. The species are as follows:

The specific chemical structure of a specific cyclodextrin dimer corresponding to the general formula (I) containing a specific biological recognition element, for example



compound 8,

disclosed in example 8 on page 74 of the specification.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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The claims are deemed to correspond to the species listed above in the following manner:

All claims are generic to the specific chemical structure of a specific cyclodextrin dimer corresponding to the general formula (I).

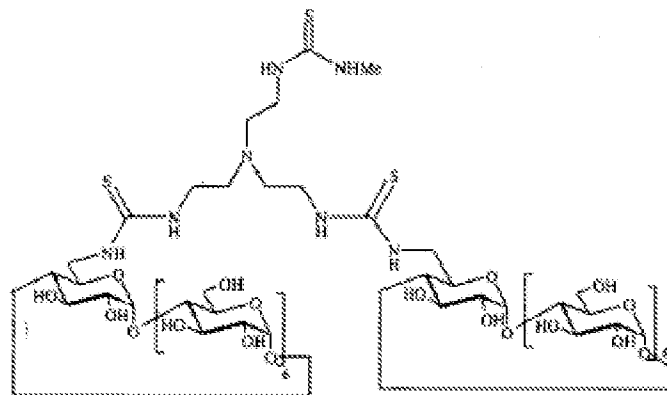
The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As recited above, said cyclodextrin dimer is not the special technical feature of a single general inventive concept. The special technical feature of Group I is the specific chemical structure of a specific cyclodextrin dimer corresponding to the general formula (I) containing a specific biological recognition element. The special technical feature of Group II is the specific chemical structure of a specific cyclodextrin dimer corresponding to the general formula (I) not containing a biological recognition element. The special technical feature of Group III is the specific chemical structure of a complex of a specific pharmacologically active agent and a specific cyclodextrin dimer corresponding to the general formula (I) containing a biological recognition element. The special technical feature of Group III is the specific chemical structure of a complex of a specific pharmacologically active agent and a specific cyclodextrin dimer corresponding to the general formula (I) not containing a biological recognition element.

If Applicant restricts to the invention of Group II or IV, Applicant is required to elect from the **second** election of species requirement.

Second election of species requirement:

This application contains claims directed to more than one species of the generic invention. The species are as follows:

The specific chemical structure of a specific cyclodextrin dimer corresponding to the general formula (I) not containing a specific biological recognition element, for



example compound 3, , disclosed in example 3 on page 63 of the specification.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

All claims are generic to the specific chemical structure of a specific cyclodextrin dimer corresponding to the general formula (I).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As recited above, said cyclodextrin dimer is not the special technical feature of a single general inventive concept. The special technical feature of Group I is the specific chemical structure of a specific cyclodextrin dimer corresponding to the general formula (I) containing a specific biological recognition element. The special technical feature of Group II is the specific chemical structure of a specific cyclodextrin dimer corresponding to the general formula (I) not containing a biological recognition element. The special technical feature of Group III is the specific chemical structure of a complex of a specific pharmacologically active agent and a specific cyclodextrin dimer corresponding to the general formula (I) containing a biological recognition element. The special technical feature of Group III is the specific chemical structure of a complex of a specific pharmacologically active agent and a specific cyclodextrin dimer corresponding to the general formula (I) not containing a biological recognition element.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jonathan S. Lau
Patent Examiner
Art Unit 1623

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623